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10/817,036	04/02/2004	Eric R. First	17675 (BOT)	2222

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,036	FIRST, ERIC R.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amended Claims 1-15 and new claims 16-22 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejections Withdrawn

1. ***Withdrawn Claim Rejections - 35 USC § 112*** Claim 3 rejected under 35 USC 112, second paragraph for reciting the limitation "is treated by increasing pigmentation" in an effort to further limit claim 2, has been obviated through amendment of claim 2 to provide antecedent basis for the claim limitations recited in claim 3.

1. ***Withdrawn Claim Rejections - 35 USC § 112*** Claim 4 rejected under 35 USC 112, second paragraph for reciting the limitation "is treated by decreasing pigmentation" in an effort to further limit claim 2, has been obviated through amendment of claim 2 to provide antecedent basis for the claim limitations recited in claim 4.

2. ***Withdrawn Claim Rejections - 35 USC § 112*** Claim 7 rejected under 35 USC 112, second paragraph for reciting the limitation "is treated by reducing a size of the melanin influenced affliction" in an effort to further limit claim 1, has been obviated through amendment of claim 7 to depend from new claim 16 which recites the term "size" and depends from claim 1.

3. ***Withdrawn Claim Rejections - 35 USC § 112*** Claim 10 rejected under 35 USC 112, second paragraph for reciting the limitation "wherein the hair color is altered by decreasing the amount of pigmentation in the hair" in an effort to further limit claim 1, has been obviated by amending the claim to depend from claim 8 rather than claim 1.

4. ***Withdrawn Claim Rejections*** Claims 8-9 and 15 rejected under 35 U.S.C. 102(b) as being anticipated by Maurer (PG-Pub 2002/0028765 A1, published March 7, 2002) has been obviated through amendment of the claims to recite an additional methods directing to altering hair color of a patient.

Response to Arguments

5. Applicant's arguments filed February 13, 2006 have been fully considered but they are not persuasive.

6. ***Maintained Rejection Claim Rejections - 35 USC § 102:*** The rejection of Claims 1-6, 11-14, and new claims 16-17, 18-22 under 35 U.S.C. 102(b) as being anticipated by M. Rodriguez Vazquez et al (2002) is traversed on the grounds that: Vazquez does not disclose the

methods step of identifying a patient in need of treatment for a melanin related affliction, where the affliction can be treated by an administration of botulinum toxin.

7. It is the position of the examiner that Vasquez et al does disclose the instantly claimed method, the method comprising the step of "identifying a patient in need of treatment for a melanin related affliction (hyper-pigmented area (see page 154, col. 1, paragraph 4) of patient skin (see page 154, "Case Report). The patient was first treated with 20% aluminum chloride hexahydrate in alcohol that was ineffective (see page 154, col. 2, last paragraph). When the first treatment did not work, the patient was in need of a treatment that would work to reduce general pain, associated with the hyper-pigmentation region that comprised hair. The pain was associated with ductal hyperplasia and dilated coils without epidermal changes (see Figure 2).

8. The patient treated by Vasquez et al was identified as a patient with a melanin related affliction, which was not successfully treated by another conventional method of treatment, but was successfully treated with botulinum toxin when the botulinum toxin was administered to the location of skin that comprised hair and hyperpigmentation.

The melanin related affliction was treated by administration of botulinum toxin, in light of Vazquez et al disclosing a 50% reduction in sweating, due to administration of botulinum toxin (see summary at end of article).

9. Applicant asserts that the reference is silent with respect to changes in pigmentation.

10. It is the position of the examiner that while the reference is silent with respect to changes in pigmentation after administration of botulinum toxin to the hyperpigmented skin lesion, the reference carried out the claimed methods steps, of identifying a patient and administering

botulinum toxin to the skin of the patient. By all comparable data, the disclosure of Vasquez et al is the same or equivalent method now claimed. No specific doses are required for the botulinum toxin administered. No distinguishing claim limitations have been set forth in the claims.

While it is true that claims 2-4 define botulinum toxin as being able (can) to increase or decrease pigmentation of the skin, the combination of claim limitations recited in the claims do not distinguish over the applied prior art. Claims 2-4 recite a natural functional characteristic of botulinum toxin, and Vasquez et al administered the same or equivalent composition administered in the method now claimed in light of the claims administering any amount of botulinum toxin, to any location of skin in need of treatment. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

With respect to the methods of claims 5-6, that administer botulinum toxin to skin or hair, the method of Vasquez et al, administered botulinum toxin to skin that comprised hair, as well as being hyper pigmented. No distinguishing claim limitations are recited in the methods of claim 5 or 6, as the claims administer any amount of botulinum toxin, to any location of skin in need of treatment of an affliction associated with melanin.

While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete

and fail to provide adequate structural properties to allow for one to identify what is being claimed.

11. Applicant requests evidence that the botulinum toxin of Vasquez et al inherently resulted in an increase or decrease of pigmentation of the skin.

12. It is the position of the examiner that Applicant 's method steps are the same or equivalent methods steps of Vasquez et al, and while Vasquez et al is silent with respect to color changes in the skin or hair, Applicant's disclosure provides definitions and evidence that botulinum when administered to hyperpigmeted skin and hair, produces pigmentation effects. The rejection is maintained for reasons of record.

13. ***Maintained Rejection*** The rejection of claims 1-14, 16-22 under 35 U.S.C. 102(e) as being anticipated by Waugh et al (US PG-Pub 2004/0220100 A1, filing date March 3, 2004) is traversed on the grounds that: Waugh "does not disclose the step of identifying a patient in need of treatment for a melanin related affliction" and does not topically apply the agent to the skin of a patient to teat a melanin related affliction.

14. It is the position of the examiner that Waugh et al, does identify a patient in need of treatment for a melanin related affliction. This patient is identified by a physician or health professional. The patient is identified, and is administered the compositions "by or under the direction of a physician or other health professional[0146]".

15. While Waugh et al do not recite the term "melanin", the melanin related affliction is defined by Waugh et al to include treating acne and skin aging which includes:

- p. [0018] "telltale signs of aging, can be caused by biochemical, histological, and physiologic changes that accumulate from environmental damage (Benedetto,

International Journal of Dermatology, 38:641-655 (1999); Stegman et al., The Skin of the Aging Face Cosmetic Dermatological Surgery, 2.sup.nd ed., St. Louis, Mo.: Mosby Year Book: 5-15 (1990)). "

- page 5, col. 1, line 1: the composition is applied to include preventing or reducing acne . Acne having a distinct color and size (instant new claim 16).
-

Applicant's definition includes prevention of a melanin related affliction, based upon the definition provided at

- [0086] The present invention is based on the discovery that local administration of a Clostridial toxin can provide significant and long lasting relief from a melanin related affliction. A Clostridial toxin used in accordance with the invention disclosed herein can inhibit transmission of chemical or electrical signals between select *neuronal groups* that are **involved in generation of a melanin related affliction.**

Applicant further defines the claimed invention to include:

- [0062] "Affliction" includes a disease, disorder, problem and/or a cosmetically undesirable state or condition in an individual. "Melanin related affliction" means an affliction which is controlled or influenced by the present or absence of melanin. Thus, melanin related afflictions include various skin pigment disorders"

Waugh et al includes within their definition the administration of botulinum toxin containing compositions to effect skin structures which include nerve endings, hair follicles, skin glands:

- " [0016] The dermis, which lies just beneath the epidermis, is 1.5 to 4 millimeters thick. It is the thickest of the three layers of the skin. In addition, the dermis is also home to most of the skin's structures, including sweat and oil glands (which secrete substances through openings in the skin called pores, or comedos), **hair follicles, nerve endings**, and blood and lymph vessels (Inlander, Skin, New York, N.Y.: People's Medical Society, 1-7 (1998)). "

Waugh et al administer the botulinum toxin to a distinct area and size through application/ administration of the botulinum toxin containing composition with a transdermal patch:

- [0021] Topical application of botulinum toxin provides for a safer and more desirable treatment alternative due to painless nature of application, **the larger treatment surface area** that can be covered, the ability to formulate a pure toxin with higher specific activity, reduced training to apply the botulinum therapeutic, smaller doses necessary to effect, and large wells of toxin are not required in order to reach a therapeutic clinical result.
- [0146] For transdermal delivery of botulinum toxin, a composition is applied topically to the skin at a location or locations where the effect is desired.

Waugh et al discloses the formulation of botulinum toxin containing compositions that further comprise:

- cosmeceutical agents, and/or [Waugh et al, paragraph 0041] with a pharmaceutically or cosmeceutically acceptable carrier to form a non-covalent complex.

Specific embodiments/formulations disclosed by Waugh et al for application of botulinum toxin to skin and skin containing hair include:

- [0144] In terms of their form, compositions of this invention may include solutions, emulsions (including microemulsions), suspensions, creams, lotions, gels, powders, or other typical solid or liquid compositions used for application to skin and other tissues where the compositions may be used. Such compositions may contain, in addition to the botulinum toxin, insulin or other biologically active agent, and the carrier molecule, other ingredients typically used in such products, such as antimicrobials, moisturizers and hydration agents, penetration agents, preservatives, emulsifiers, natural or synthetic oils, solvents, surfactants, detergents, gelling agents, emollients, **antioxidants**, fragrances, fillers, thickeners, waxes, odor absorbers, dyestuffs, **coloring agents**, powders, viscosity-controlling agents and water, and optionally including anesthetics, anti-itch actives, botanical extracts, **conditioning agents, darkening or lightening agents**, glitter, humectants, mica, minerals, polyphenols, silicones or derivatives thereof, **sunblocks**, vitamins, and phytomedicinals.

Therefore Waugh et al still anticipates the instantly claimed invention that administers botulinum toxin to the skin or hair of an identified patient of the prevention or treatment of age related

16. The rejection of claims 1-2,4-7, 11-12, 14, 16 under 35 U.S.C. 102(e) as being anticipated by Pastan et al (US PG-Pub 2004/0087772 A1) is traversed on the grounds that: "the Pastan reference is non-enabling with respect to the method of treating melanoma with a botulinum toxin" as the references "does not teach the appropriate dose of the chimera to administer to treat melanoma".

17. It is the position of the examiner that the instantly claimed invention may administer any dose of botulinum toxin to the patient to treat a melanin related affliction. The claimed invention need not eradicate the melanin related affliction, as treatment encompasses an attempt to minimize symptoms, partial protection and total eradication. The claimed invention need not eradicate melanoma cells, but need only administer botulinum toxin to a patient.

18. Pastan et al discloses at paragraph:

- [0217] Thus, a typical pharmaceutical immunotoxin composition of the present invention for intravenous administration would be about 0.1 to 10 mg per patient per day. Dosages from 0.1 up to about 100 mg per patient per day may be used, particularly if the drug is administered to a secluded site and not into the circulatory or lymph system, such as into a body cavity or into a lumen of an organ Actual methods for preparing administrable compositions will be known or apparent to those skilled in the art and are described in more detail in such publications as REMINGTON'S PHARMACEUTICAL SCIENCE, 19TH ED., Mack Publishing Company, Easton, Pa. (1995).

  The claimed invention administers any amount to the patient. No doseages are claimed.

Pastan et al still anticipates the instantly claimed invention .

New Grounds of Objection/Rejection
Claim Objections

19. Claim 7 is objected to because of the following informalities: Claim 7 should depend from a prior claim (lower number) and not from a later presented claim; Claim 7 depends from claim 16 which is a later presented claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

20. Claims 2-4, 8-10, 15, 16, 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2-4 and 18-21 administer botulinum toxin to increase or decrease the pigmentation of the **skin**. How the same composition can be administered to the same location, and in the same dosage amount and result in two divergent effects when administered to the same patient with the same melanin related afflictions does not set forth a combination of claim limitations that are internally consistent; the newly submitted combination of claim limitations are contradictory. Applicant's invention is not clearly nor distinctly claimed. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claims 8-10 administer botulinum toxin to increase or decrease the pigmentation of **hair**. How the same composition can be administered to the same location, and in the same dosage amount and result in two divergent effects when administered to the same patient with the same melanin related afflictions does not set forth a combination of claim limitations that are internally consistent; the newly submitted combination of claim limitations are contradictory. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the

specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claim 15 is directed to a method of hair removal through administration of botulinum toxin to the hair of the patient. Schwartz et al (US Pat. 6,299,893) administers botulinum toxin to a patient to prevent hair loss. The instantly claimed invention that is directed to hair removal, is not distinctly claimed in light of the fact that the prior art teaches botulinum toxin to prevent hair loss and not enhance hair removal. Applicant's invention is not clearly nor distinctly claimed. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claim 16 recites the phrase "presents as a skin area having a distinct color and size" and depends from claim 1 which does not administer the botulinum toxin to a skin area recited in claim 16, but to any location on the patients skin. The phrase recited in claim 16 modifies the preamble of the claim, and not the administering step. The terms "presents" and "area" do not evidence antecedent basis in claim 1. What is a distinct color; What is a distinct size; in light of the fact that claim 1 administers the botulinum toxin to any location on the individuals skin and is not limited to administration to any specific location?

Double Patenting

21. Claim 1 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 22. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). While claim 22 recites the term native, and claim 1 does not, the administered botulinum toxins cover the same thing.

22. Claims 1 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40 and 45 of copending Application No. 10/929,040. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention is directed to a genus of methods that by definition in the instant specification the claimed species recited in claims 40 and 45 of US Application 10/929,040. The copending species directed to treating a melanoma anticipates the instantly claimed genus of treating any type of melanin related affliction and is an obvious species of the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
May 2, 2006

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